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## Atypical Antipsychotic Drugs for Schizophrenia: Access, Reimbursement and the Struggle for Parity

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## **Atypical Antipsychotic Drugs for Schizophrenia: Access, Reimbursement and the Struggle for Parity**

By Sandra Kim (Hutt - Winter 2001)

Abstract:

This paper discusses the impact of schizophrenia on American society and advocates for health care reform to address the lack of access by the mentally ill to a class of innovative drugs, called “atypical anti-psychotics.” Atypical anti-psychotic drugs, including clozapine, risperidone and olanzapine are crucial for the treatment of both the positive and negative symptoms of schizophrenia and should be made available as first-line treatments for schizophrenics. Current health care policies and reforms provide facially attractive benefits, but lack significant practical benefits, resulting in obstacles to access to these life-changing medications. Health care reforms providing adequate reimbursement for these medications, and thereby opening access to them on a first-line basis, would in fact *relieve* financial pressures on our health care system instead of creating further strain on scarce resources by reducing funds spent on hospitalization and other medical resources.

## **Introduction**

Mental health research and pharmaceutical innovation have developed a class of drugs referred to as “atypical antipsychotics,” which are used for the treatment of severe schizophrenics who are considered treatment-resistant to traditional or conventional antipsychotic medications, or who experience side-effects severe enough to require that the patient discontinue use of conventional antipsychotics. These atypical antipsychotics are tremendously effective in combating the symptoms of schizophrenia while avoiding the severe side-effects often experienced through treatment with conventional antipsychotics. Despite the existence and availability of such drugs on the pharmaceutical market, both public and private mental health care policy in the United States create barriers to access to these treatments. Stigma and prejudice associated with schizophrenia, and concerns about the high cost of the atypicals stand out as the primary culprits for the inequitable distribution of resources for mental health care as compared to resources devoted to the treatment of more visible and politically or socially palatable “wholly physiological” illnesses.

Access to atypical antipsychotic medications as first-line medications is crucial to the treatment of schizophrenics for a number of reasons. First of all, the conventional or traditional antipsychotics carry with them severe and potentially irreversible side-effects that greatly impact the quality of a schizophrenic patient’s life. Secondly, the side-effects of the conventional antipsychotics lead to the disturbing consequence of poor patient compliance with treatment, thereby increasing the risk of harmful relapse episodes by patients. Third, the traditional treatments do not relieve the negative symptoms of the disorder, resulting in the reduction of delusions and hallucinations, but doing little or nothing to correct the anti-social behavior exhibited by schizophrenics. This anti-social behavior, which is largely responsible for the inability of schizophrenics to function in their communities, must be remedied in order to reintegrate individuals suffering from schizophrenia into society as self-sufficient, functioning members of their communities.

As the country increases its awareness of the consequences of schizophrenia on its citizens as well as on

society as a whole, reform of current health care policy will be necessary in order to address the resource needs of the long-neglected population of schizophrenics. Though some efforts have been made to equalize benefits provided to patients suffering from mental health disorders versus what many claim are distinctly physiological disorders, the reforms made to date have been largely symbolic and ineffective in practice.

Significantly, the plea for access to necessary atypical antipsychotic treatments differs from the suggestion that these medications should become freely available to *every* schizophrenic or that the prescription of such medications should become routinized so as to make access similar to that of any other prescription medication. Reform of current policy toward distribution of these medications should merely facilitate physician-patient independence to determine which treatments are most promising for each individual patient. Oversight of the distribution of these drugs, and their marketing should certainly be permitted and indeed, encouraged or mandated government regulation to ensure that proper safety precautions are taken. The “facilitation” of physician-patient interactions and of physician and patient independence does not, however, come easily. Systemic structures, including managed care, have greatly impacted the ability of physicians to make independent decisions regarding the care of their patients. In the area of mental health care, this fact rings especially true, and in the narrower area of atypical antipsychotic treatments, even truer still. The high cost of atypical antipsychotic medications, coupled with their monitoring requirements – in some cases mandating weekly blood tests to ensure the maintenance of the patient’s blood cell counts<sup>1</sup> – make these medications some of the most expensive on the pharmaceutical market. However, cost concerns may and should be addressed through means other than by barring access to these vital treatments.

The increased availability and access to atypical antipsychotic treatments will benefit not only the schizophrenic community, but will also benefit society as a whole by allowing a large population of persons to reintegrate

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<sup>1</sup>NOVARTIS PHARMACEUTICALS CORPORATION, CLOZARIL PRESCRIBING INFORMATION (2001) at 5.

with society by securing employment and functioning as otherwise productive members of their communities instead of representing a drain on health care and other welfare resources. “[N]early 30 percent (\$19 billion) of schizophrenia’s costs involves direct treatment *and the rest is absorbed by other factors* – lost time from work for patients and care givers, social services and criminal justice resources. . . [S]chizophrenia affects one percent of the population, accounts for a fourth of all mental health costs and takes up one in three psychiatric hospital beds. Since most schizophrenia patients are never able to work, they must be supported *for life* by Medicaid and other forms of public assistance.”<sup>2</sup> Clearly, factors other than the price of the drugs alone enter into the equation of determining the cost-effectiveness of providing appropriate medications for the treatment of schizophrenia. The seemingly exorbitant costs of the atypical antipsychotic drugs needed to effectively treat schizophrenia may be more than recouped through the effective reintegration of those suffering from schizophrenia into society, ultimately resulting in a net conservation of resources.

Furthermore, it has been suggested that the high price of atypical antipsychotic treatments may more appropriately be attributed to the premium placed on such drugs due to our tort laws and the increasingly litigious nature of American society. The combination of the two phenomena creates an incentive for drug manufacturers to place barriers to access in the form of increased costs in order to build in the price of possible tort liability for these effective but high-risk drugs.

Some combination of mental health parity laws requiring a non-discrimination standard of providing health care benefits, and the relaxing of tort liability for drug manufacturers who produce beneficial, yet high risk, medications would benefit patients in desperate need of these treatments. Such new policies may provide a much needed incentive to drug manufacturers to develop *still other* drugs that may be even more effective in treating schizophrenic patients. Likewise, a relaxing of tort liability with regard to the use of the atypical antipsychotics would reduce the incentive for physicians to treat schizophrenic patients with inferior, con-

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<sup>2</sup>The Schizophrenia Homepage, *U.S. Health Official Puts Schizophrenia Costs at \$65 Billion*, (May 9, 1996) (summarizing statements made by Richard Wyatt, M.D., chief of neuropsychiatry, National Institutes of Mental Health, made at an annual meeting of the American Psychiatric Association) (emphasis added) at <http://www.schizophrenia.com/news/costs1.html>.

ventional antipsychotics for the purpose of avoiding medical malpractice liability. Instead, physicians would be permitted to use objective criteria to make informed decisions as to which treatment would provide the greatest benefits to a given patient. Our health care laws should facilitate physician-patient interactions when dealing with mental illnesses and not impede physician judgment through managed care, tort liability, or cost concerns that lie outside the realm of concern for the patient's ultimate well-being.

## **A. The Problem of Schizophrenia**

### **I. Background Information**

Schizophrenia presents a serious health care problem in the United States and worldwide. The National Institute of Mental Health estimates that about one in one hundred people in the United States will develop schizophrenia during his or her lifetime.<sup>3</sup> Among developed nations, schizophrenia, along with other mental disorders, has become one of the leading causes of disability.<sup>4</sup> In addition to the symptoms the disorder directly imposes on its victims, other correlating conditions and factors jeopardize the lives of schizophrenic patients. Seven to ten percent of schizophrenic patients are estimated to commit suicide.<sup>5</sup> Schizophrenics also suffer from natural diseases and physiological ailments such as cardiovascular illness at rates that exceed those of the average population.<sup>6</sup> Thus, the illness carries with it definite physiological consequences as well as the less tangible "purely mental" symptoms of the disorder. Moreover, a significant body of evidence suggests that schizophrenia is a biological disorder or disease of the brain.<sup>7</sup> This new information casts

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<sup>3</sup>Margie Patlak, *Schizophrenia: Real Lives Ravaged by Imaginary Terror*, FDA CONSUMER MAGAZINE Sept. - Oct. 1997, available at [http://www.fda.gov/fdac/features/1997/697\\_schiz.html](http://www.fda.gov/fdac/features/1997/697_schiz.html).

<sup>4</sup>Michael D. Brophy, *Emerging Medical-Legal Issues in the Prescriber-Patient*, 18 NO. 8 MED. MALPRACTICE L. & STRATEGY 4, (2001).

<sup>5</sup>Milt Freudenheim, *Seeking Safer Treatments for Schizophrenia*, N.Y. TIMES, Jan. 15, 1992, at D5. See also Brophy *supra* note 4.

<sup>6</sup>Transcript of Food and Drug Administration Center for Drug Evaluation and Research Psychopharmacologic Drugs Advisory Committee, July 19, 2000 at 22. [ Hereinafter *Advisory Committee Transcript* ].

<sup>7</sup>Richard E. Gardner, III, *Mind Over Matter?: The Historical Search for Meaningful Parity Between Mental and Physical Health Care Coverage*, 49 EMORY L.J. 675 ,683 (2000) ("Though studies have shown varied results, most scientists agree that schizophrenics have lighter than normal brains with enlarged ventricles. The schizophrenic's brain also typically has smaller frontal lobes or a reduction in neurons in the frontal lobes, and is characterized by more of a random neural organization than a normal brain's 'consistent parallel orientation.' These findings are reflected in the statement by Dr. E. Fuller Torrey, who

suspicion on the argument that disparate coverage provisions often encountered in health care plans are justified because of the entirely “mental” nature of schizophrenia as compared to other physical disorders.

Current mental health care policy should address the need for effective treatment of this debilitating and life-threatening disorder. The one percent figure of people likely to develop schizophrenia stands to increase in the near future, rendering the problem of lack of adequate treatment options an even greater problem. Demographic changes in our country increase the potential for incidence of the disorder as a percentage of the general population. As the average life expectancy grows and the elderly become an increasingly numerous population, health care policy should address the problem of disability due to mental illness, especially in those individuals over 65 years of age. Conditions such as schizophrenia, among others, will pose particular problems for this group.<sup>8</sup> If left unrecognized and/or untreated, late-life schizophrenia may severely impair or even be fatal to those it afflicts.<sup>9</sup> Thus, barriers to access to treatment established by government regulation or managed care pose a particular threat to the welfare of schizophrenic patients. “There is some literature which suggests that people with schizophrenia do not appreciate that they have the condition about 50 percent of the time. So now we have a person who may not appreciate that their perception of reality does not jive with other people, and we introduce limitations on how well they access services. . . There is little surprise, then, that we result in a situation where people delay treatment, which worsens the course of their illness, and they do not have access to treatment as soon as possible.”<sup>10</sup> Reform of existing mental health care may address the problem of treatment delays that may prove seriously or even

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concluded that the ‘evidence is now overwhelming that the brains of persons who have schizophrenia are, as a group, different from brains of persons who do not have this disease.’”)

<sup>8</sup>Medicare Mental Health Modernization Act of 2001, H.R. 1522/S. 690 107th Cong. 1<sup>st</sup> session (2001) (currently referred to Subcommittee on Health).

<sup>9</sup>*Id.* at 3.

<sup>10</sup>Statement by Dr. Kenneth Duckworth, deputy commissioner, Massachusetts Department of Mental Health, Boston, MA, before Hearing of the Committee on Health, Education, Labor, and Pensions, United States Senate, 106<sup>th</sup> Congress, 2<sup>nd</sup> Session on Examining Mental Health parity issues, including S. 796, to provide for full parity with respect to health insurance coverage for certain severe biologically-based mental illnesses and to prohibit limits on the number of mental illness-related hospital days and outpatient visits that are covered for all mental illnesses, May 18, 2000, p. 87.

permanently damaging to the lives of sufferers of this disorder.

The fact that full recovery from schizophrenia rarely occurs underscores the need for the availability of safe and effective drugs to treat the symptoms of the disease. The incidence of schizophrenia has the potential to significantly impact United States health care policy. One figure estimates that approximately 3 million people in the United States suffer from schizophrenia.<sup>11</sup> In addition, the disorder accounts for 25 percent of all hospital bed days in the United States!<sup>12</sup> Moreover, due to its chronic and debilitating nature, schizophrenia accounts for approximately 2.5 percent of all United States health care costs, 10 percent of all permanently and totally disabled citizens, and 20 to 30 percent of the homeless population.<sup>13</sup> Lastly, evidence shows that schizophrenics, due to a combination of the above factors, including under-treatment of the disorder, have an average 20 percent shorter life span than persons in the general population.<sup>14</sup>

Development of schizophrenia typically appears in adolescence or in the twenties in men and in the twenties or early thirties in women. Children rarely demonstrate schizophrenic symptoms. Indeed, many schizophrenics exhibit entirely normal behavior during childhood.<sup>15</sup> The disease is characterized by a series of symptoms, which include those generally referred to as “positive symptoms” (delusions and hallucinations), “negative symptoms” (anti-social behavior and loss of emotional response), and “cognitive symptoms” (disordered thought and attention deficits).<sup>16</sup> Common manifestations of hallucinations in schizophrenics include the hearing of voices that no one else can hear that tell a patient what to do, describe what the patient is doing,

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<sup>11</sup> *Advisory Committee Transcript supra* note 6 at 21.

<sup>12</sup> *Id.* at 21-22.

<sup>13</sup> Anthony F. Lehman, *Quality of Care In Mental Health: The Case of Schizophrenia; New therapies show great promise in treating persons with schizophrenia. The challenge is to get the treatment to the patient*, HEALTH AFFAIRS (The People-To-People Health Foundation, Inc.) (1999) (citing A. Rupp and S. Keith, *The Costs of Schizophrenia: Assessing the Burden*, PSYCHIATRICS CLINICS OF NORTH AMERICA 16, No. 2 (1993): 413-23).

<sup>14</sup> *Advisory Committee Transcript supra* note 6 at 27.

<sup>15</sup> Patlak *supra* note 3.

<sup>16</sup> CORTEX PHARMACEUTICALS, INC., ANNUAL REPORT 6-7 (2000). <http://www.cortexpharm.com/pdfs/CORX10KSB00.pdf>.



warn the patient of danger, or carry on conversations with the patient. Delusions of persecution or grandeur are also common among schizophrenics.<sup>17</sup>

Generally speaking, a diagnosis of schizophrenia requires the demonstration by a patient of two or more of the above symptoms during a one-month period.<sup>18</sup> Furthermore, a substantial inability to work or socialize for at least six months would indicate to a physician the strong possibility of schizophrenia in the patient.<sup>19</sup>

## II.

### Conventional Antipsychotic Treatments for Schizophrenia and the Need for Access to A

Initially, schizophrenics turned to treatment for their positive symptoms in drugs generally characterized as “neuroleptics” or “conventional antipsychotics,” which functioned chemically by blocking the binding sites for the neurotransmitter, dopamine.<sup>20</sup> These drugs were largely developed in the 1950s and 1960s.<sup>21</sup> The first conventional antipsychotic, chlorpromazine (marketed under the name “Thorazine”), began a period that included the development of more than a dozen similar drugs including haloperidol (marketed under the name “Haldol”), thioridazine (marketed as “Mellaril”), loxapine (marketed under the name “Loxatane”), and molindone (marketed as “Moban”).<sup>22</sup> The chemical process of these medications causes the

These conventional antipsychotics continue to be used today. These drugs made the significant contributions of treating the positive symptoms of the disease, as well as reducing the need for chronic hospitalization

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<sup>17</sup>Patlak *supra* note 3.

<sup>18</sup>DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS, Revised (DSM III-R) (American Psychiatric Press, Washington D.C., 3d ed. 1987).

<sup>19</sup>Patlak *supra* note 3. One should note, however, that schizophrenic symptoms might develop due to the use of drugs such as phencyclidine hydrochloride (PCP) or chronic high doses of amphetamines. A physician would rule out such drugs as the cause of such symptoms before making a firm diagnosis of schizophrenia for the patient.

<sup>20</sup>Patlak *supra* note 3.

<sup>21</sup>CORTEX PHARMACEUTICALS, INC., *supra* note 16 at 7.

<sup>22</sup>Patlak *supra* note 3.

of schizophrenics. However, the conventional antipsychotics carry with them severe and sometimes life-threatening side-effects. Common side-effects of the conventional antipsychotics include “extrapyramidal signs,” which appear as uncontrollable muscle spasms or tremors resembling symptoms commonly observed in those with Parkinson’s disease.<sup>23</sup> These side-effects lead to poor quality of life for patients using the drugs, and cause the additional problematic result of poor patient compliance with continuing treatment with their medications. “Given [the] many reports of how normals react to single low doses of neuroleptics, one may wonder how it is that so many schizophrenic patients can tolerate them at all.”<sup>24</sup>

Other largely dose-dependent side-effects of conventional antipsychotics include drowsiness, restlessness, cramps, dizziness, stiffness of the limbs, dry mouth, impotence, menstrual irregularities, or blurring of vision.<sup>25</sup> Moreover, long-term use of these drugs may cause a condition known as “tardive dyskinesia,” which is a disorder in which the patient suffers involuntary movements or tics.<sup>26</sup> The greater the period of treatment with these drugs, the greater the risk of developing tardive dyskinesia. More than 25 percent of schizophrenic patients taking conventional antipsychotics for over five years develop the disorder.<sup>27</sup> Tardive dyskinesia occurs in up to 70 percent of high-risk schizophrenic patients such as the elderly, making the use of traditional antipsychotics a clear risk for treating such populations.<sup>28</sup> And, as noted earlier, due to demographic changes, this group stands to increase as a percentage of the general population. The risk of developing tardive dyskinesia and the likelihood that it will become irreversible increases as the duration of treatment and dosages increase.<sup>29</sup> Moreover, there is no known treatment for established cases of the disorder aside from withdrawal from the use of the responsible drug.<sup>30</sup>

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<sup>23</sup>NAT’L INSTITUTE OF MENTAL HEALTH, *Improving Treatments, Preventing Relapse: Atypical Antipsychotic Medications* (June 1, 2001) at <http://www.nimh.nih.gov/sciadvances/Atypical.cfm>.

<sup>24</sup>Weidan, Shaw & Mann, *Causes of Neuroleptic Noncompliance*, 16 PSYCHIATRIC ANNALS 571 (1986). Neuroleptic is another name for antipsychotic drugs.

<sup>25</sup>Patlak *supra* note 3.

<sup>26</sup>Patlak *supra* note 3.

<sup>27</sup>Patlak *supra* note 3.

<sup>28</sup>*Advisory Committee Transcript supra* note 6 at 23.

<sup>29</sup>NOVARTIS, *supra* note 1 at 9.

<sup>30</sup>*Id.*

The conventional antipsychotics therefore have severe limitations for those who experience side-effects with their use. Significantly, these drugs also do not alleviate the symptoms of cognitive dysfunction, apathy or other negative symptoms that are largely responsible for the social disability associated with schizophrenia.<sup>31</sup> Cognitive impairment, which may affect attention, memory, and executive function, can present “insurmountable social and vocational obstacles to patients” suffering from schizophrenia.<sup>32</sup> Thus, the traditional treatments are limited in their ability to solve for the considerable problem of many schizophrenics’ inability to reintegrate into society and regain independence and control of their lives.

The use of *atypical* antipsychotic treatments, however, “provides maximum control of both positive and negative symptoms, limits cognitive impairment, and gets patients back to school and to work quickly, so that they don’t become dropouts and loners.”<sup>33</sup> Prior to the availability of atypical antipsychotic treatments, 90 percent of patients taking the conventional antipsychotics possessed functional disabilities that hindered them from working. The atypical antipsychotics give many the option to work for the first time since the onset of their conditions.<sup>34</sup>

### III. Atypical Antipsychotics: The Need for Them and FDA Regulation

The atypical antipsychotics emerged in the 1960s, when they received the name “atypical” because “they could be administered in doses that alleviated positive symptoms without causing the neurological side-effects associated with the conventional agents.”<sup>35</sup> Atypical antipsychotics, like their predecessor conventional antipsychotics, also affect the neurotransmitter dopamine, but work further to affect the neurotransmitter serotonin. The atypical antipsychotics, specifically, decreased the incidence of extrapyramidal symptoms, diminished hyperprolactinemia,<sup>36</sup> demonstrated superior efficacy in refractory schizophrenia, lessened the

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<sup>31</sup>Brophy *supra* note 4.

<sup>32</sup>Brendan Ross & Leigh Ann Ramsey, *Novel Antipsychotic Drugs in the Management of Schizophrenia*, 145 DRUG TOPICS No. 9, 75 (2001).

<sup>33</sup>Lynne Lamberg, *New Medications Aid Cognition in Schizophrenia*, 280 J. AM. MED. ASS’N No. 11, (1998).

<sup>34</sup>*Id.*

<sup>35</sup>Brophy, *supra* note 4. (quoting Douglas Mossman, M.D., & Douglas S. Lehrer, M.D., *Conventional and Atypical Antipsychotics and the Evolving Standard of Care*, 51 PSYCHIATRIC SERVICES, No. 12 (2000).

<sup>36</sup>Hyperprolactinemia is a pituitary disorder characterized by an excess of the hormone pro-

hallucinations and bizarre behavior of patients, and had the substantial added benefit of relieving negative symptoms of the disorder<sup>37</sup> (though the FDA has not yet determined the veracity of the superiority of the atypical antipsychotics in treating negative symptoms).<sup>38</sup>

Three major atypical antipsychotics appeared in the 1960s to 1980s.<sup>39</sup> Clozapine was the first synthesized in 1960, and by the late 1960s entered distribution in European markets.<sup>40</sup> Clozapine was initially developed and patented by Sandoz Ltd. of Switzerland, and marketed in the United States by the subsidiary Sandoz Pharmaceutical Corp, under the popular brand name “Clozaril.”<sup>41</sup>

The atypical antipsychotics have been widely adopted in North America and account for three-fourths of all antipsychotic prescriptions.<sup>42</sup> They are more expensive than the traditional antipsychotics, but the cost is largely accepted as justified by advocates for the treatments because they are believed to be more effective and better tolerated.<sup>43</sup> Substantial evidence suggests clozapine’s efficacy in patients who have received unsuccessful or ineffective treatment through the use of conventional neuroleptics.<sup>44</sup> About one-third to one-half of those who take clozapine respond positively to the drug.<sup>45</sup> During clinical trials, clozapine reduced psychotic symptoms in 30 percent<sup>46</sup> to 65 percent<sup>47</sup> of the patients treated.

lactin. PITUITARY NETWORK ASSOCIATION, *Hyperprolactinemia and Prolactinomas*, (2001) at <http://www.pituitary.com/PituitaryNewsUpdates/PituitaryNews/may4/HyperprolactinemiaProlactinomasFactSheet>.

<sup>37</sup>Ross & Ramsey *supra* note 32.

<sup>38</sup>Patlak *supra* note 3.

<sup>39</sup>CORTEX PHARMACEUTICALS, INC., *supra* note 16 at 7.

<sup>40</sup>Judy Folkenberg, *New Schizophrenia Drug: Balancing Hope with Safety*, FDA CONSUMER MAGAZINE, (June 1990), available at <http://www.fda.gov/bbs/topics/CONSUMER/CON00055.html>.

<sup>41</sup>Robert N. Swidler, *Medical Innovations and Ethics: A State Government Perspective*, 57 ALB. L. REV. 655, 668 (1994). See also Carl Salzman, *Mandatory Monitoring for Side-effects: The “Bundling” of Clozapine*, 323 NEW ENG. J. MED 827, 827 (1990).

<sup>42</sup>Some clinicians, however, continue to prescribe the conventional antipsychotics, either because of their comfort level with using the drugs and/or their belief that the drugs truly are superior to the newer antipsychotics. Brophy *supra* note 4.

<sup>43</sup>Brophy *supra* note 4.

<sup>44</sup>Ramsey & Ross *supra* note 32 (“In one trial of treatment-resistant patients, clozapine therapy demonstrated a 30% response rate after six weeks, compared with a 4% rate for a conventional drug. In longer-term studies, approximately 70% of such patients received significant benefits from Clozapine use. Clozapine produced greater improvements in negative or deficit symptoms, such as emotional withdrawal, blunted affect, and motor retardation, as well. Cognitive function improved in responders, but benefits were modest.”).

<sup>45</sup>Catherine E. Blackburn, *New Directions in Mental Health Advocacy? Clozapine and the Right of Medical Self-Determination*, 14 MENTAL & PHYSICAL DISABILITY L. REP. 453, 453 (1990).

<sup>46</sup>*Id.* at 453 (citing Honigfeld, G. & Patin, J., *A Two-Year Clinical and Economic Follow-Up of Patients on Clozapine*, 41 HOSP. & COMMUNITY PSYCHIATRY 882, 883 (1990)).

<sup>47</sup>*Id.* (citing Naber & Hippus, *The European Experience with Use of Clozapine*, 41 HOSP. & COMMUNITY PSYCHIATRY 886,

The clinical testing of clozapine showed a virtual absence of extrapyramidal symptoms. Clozapine's weak dopamine blocking effect as compared to the conventional antipsychotics, may explain its lesser side-effects. Furthermore, no reports (as of June of 2001) of tardive dyskinesia have been directly attributable to the use of clozapine.<sup>48</sup> Thus, testing of clozapine suggests that its use may avoid the risk of developing tardive dyskinesia, a potentially irreversible consequence of treatment with the conventional antipsychotics.

Clozapine does, however, possess its own unique set of risks and side-effects. The FDA halted the initial clinical trial of clozapine in the 1970s due, primarily, to the risk of severe side-effects. In 1975, post-market reports from Finland informed the United States that eight schizophrenic patients had died from complications associated with agranulocytosis,<sup>49</sup> a fatal blood disorder<sup>50</sup> in which the patient's bone marrow ceases to produce white blood cells, which are necessary in fighting infection.<sup>51</sup> The drug was subsequently re-marketed in Europe after coupling it with a monitoring program.<sup>52</sup>

Agranulocytosis occurs in an estimated 1.3 percent of patients who have used the drug for a period of one year.<sup>53</sup> To give some perspective on the relative risk of this disorder due to the use of clozapine, agranulocytosis occurs over 100 times more often with clozapine than with a conventional antipsychotic, such as chlorpromazine.<sup>54</sup> As of December 31, 1989, 32 percent of the 149 worldwide reported cases of agranulocytosis resulted in death. However, few of these deaths occurred after 1977, when the effects of clozapine on inducing agranulocytosis became more widespread and at which time stricter monitoring of white blood cell counts became more widely practiced.<sup>55</sup> Still, "it is unknown at present what the case fatality rate will

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887, 888 (1990)).

<sup>48</sup>NOVARTIS *supra* note 1at 9.

<sup>49</sup>Chris Spolar, *New Schizophrenia Drug Arouses Furor Over Cost; Debate Focuses on Control of Monitoring System*. WASH. POST, July 31, 1990, at Z7.

<sup>50</sup>A blood disorder characterized by a reduction in white blood cells, which leaves the patient vulnerable to infection. A common cold could be fatal to a patient with this disorder. Folkenberg *supra* note 40.

<sup>51</sup>Blackburn *supra* note 45 at 454.

<sup>52</sup>Spolar *supra* note 49.

<sup>53</sup>NOVARTIS *supra* note 1at 4.

<sup>54</sup>Blackburn *supra* note 45 at 454.

<sup>55</sup>NOVARTIS *supra* note 1at 4.

be for Clozaril (clozapine) induced agranulocytosis, despite strict adherence to the required frequency of monitoring.”<sup>56</sup>

Vigilant monitoring of patients and early detection of agranulocytosis remains the key to preventing fatal results.<sup>57</sup> In clinical trials, patients recovered from the disorder when they ceased taking the medication.<sup>58</sup> However, if bone marrow depression is undetected at an early stage, the disorder becomes irreversible and fatal.<sup>59</sup>

Furthermore, clozapine causes a seemingly dose-dependent risk of seizures, affecting approximately five percent of users during clinical testing who had taken the drug for one year.<sup>60</sup> The product literature advises against the prescription of clozapine to patients with a history of seizures or “other predisposing factors.” Furthermore, patients using the drug should not engage in activities that might become dangerous should a sudden loss of consciousness occur, such as driving, the operation of complex machinery, swimming, etc.<sup>61</sup> Other conditions possibly related to clozapine use (though their relationship to the drug is less certain than those of seizures and agranulocytosis) are various adverse cardiovascular and respiratory effects including tachycardia, hypotension, and neuroleptic malignant syndrome.<sup>62</sup>

Despite the risks associated with the use of clozapine, the drug was reintroduced in the 1980s when the FDA approved it for compassionate reasons so that it could be used in patients who were unable to undergo treatment with traditional neuroleptics.<sup>63</sup> The FDA approved clozapine for use by those people who had tried, but had experienced unsatisfactory results (such as lack of efficacy or significant side-effects) with conventional antipsychotics. Current product literature for Clozaril states that the drug has been approved

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<sup>56</sup>*Id.*

<sup>57</sup>No deaths had occurred in the United States as a result of use of Clozapine (as of 1987) due to the reversible nature of the disorder with early detection. *New Drug is Said to Help Severe Schizophrenics*, N.Y. TIMES, May 15, 1987 at B12.

<sup>58</sup>Folkenberg *supra* note 40.

<sup>59</sup>Blackburn *supra* note 45 at 454.

<sup>60</sup>NOVARTIS *supra* note 1 at 7.

<sup>61</sup>NOVARTIS *supra* note 1 at 7.

<sup>62</sup>NOVARTIS *supra* note 1 at 8. Due to the limited information on the effects of clozapine on the occurrence of these conditions, they will not be discussed in further detail in this piece.

<sup>63</sup>CORTEX PHARMACEUTICALS, INC., *supra* note 16 at 7; Folkenberg *supra* note 40.

for “the management of severely ill schizophrenic patients who fail to respond adequately to standard anti-psychotic drug treatment.”<sup>64</sup> As for seizures, simply lowering the dosage or treating with anti-convulsant drugs typically relieves the problem.<sup>65</sup>

Due to the dangers associated with the use of clozapine, careful monitoring must accompany treatment with the drug. Patients who do not demonstrate an acceptable level of clinical response over an extended period of time should cease treatment with clozapine.<sup>66</sup> The product literature recommends that physicians considering the use of clozapine on a patient first perform two trials - “each with a different standard anti-psychotic drug product, at an adequate dose, and for an adequate duration” - before making a determination that conventional antipsychotics are insufficient for treatment of the patient.<sup>67</sup>

This recommendation as stated in the product literature demonstrates one of the ways in which atypicals are currently reserved for second-line, instead of first-line treatments. As discussed later in this essay, such a requirement creates inefficiencies in resource expenditure and more importantly, places patients at serious risk of developing harmful conditions attributed to the use of the conventional antipsychotics. Physicians should be given the liberty to treat patients on a case-by-case basis, choosing whichever treatments the physician and patient decide would be most advantageous to the health of the patient. However, current health care policy and even reforms tend to reserve reimbursement for approved uses, such as those stated in the product literature, which thereby limit the options available to patients who lack funding sufficient to independently cover the price of medication.

From the beginning, clozapine was eyed with suspicion due to the hazards accompanying the drug. However, the incredible benefits derived from the use of it and other atypicals have slowly opened pathways to obtain-

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<sup>64</sup>Blackburn, *supra* note 45 at 453 (quoting Product Literature supplied with Clozaril, the trade name for clozapine, manufactured by Sandoz Pharmaceuticals Corp.).

<sup>65</sup>Folkenberg *supra* note 40.

<sup>66</sup>NOVARTIS *supra* note 1 at 3. The product literature recommends that even patients who respond beneficially to clozapine should receive periodic re-evaluations of their need for continuing treatment due to the risks of side-effects.

<sup>67</sup>NOVARTIS *supra* note 1 at 4.

ing the medications. In 1983 Sandoz (n/k/a “Novartis AG”) applied for FDA approval to market Clozaril for treatment-resistant schizophrenia. However, the FDA’s conservative stance toward drug approvals led to the denial of Sandoz’s request, due in large part to the danger of agranulocytosis in patients taking the drug. An FDA advisory committee composed of independent outside consultants, however, encouraged the company to pursue proof of the drug’s effectiveness in treating schizophrenics whose symptoms were not reduced by then approved drugs. Thus, the FDA and Sandoz formulated a large research study to test the drug’s effectiveness.<sup>68</sup>

The FDA approved Clozaril in 1989 and subsequently approved a new formulation of Clozaril in 1997.<sup>69</sup> “The severity and hopelessness of unremitting chronic schizophrenia was an important factor in the decision to approve Clozaril, despite the fact that it is associated with some serious risks,” said Paul Leber, M.D., FDA’s director of the division of neuropharmacological drug products. Although the FDA noted that there was no objective way of measuring the risk versus the benefits of approving the drug, the FDA considered approval of the drug a risk worth taking.<sup>70</sup> Patient advocate groups likewise considered the risks associated with the drug insubstantial considering the benefits the drug might contribute to patients in need. “We think that the potential risk for death is worth the benefit Clozaril brings for people who have almost no life of their own,” stated a representative of the National Alliance for the Mentally Ill, an organization made up of patients and the relatives of the severely mentally ill.<sup>71</sup> Though the FDA and patient advocates had stated that the use of clozapine represented a risk they were willing to take due to the enormous potential benefits that the drug could provide for schizophrenics, laws and policies by government, drug manufacturers and health care providers alike established significant obstacles to access to the medication that were severe enough to prohibit many from benefiting from treatment with clozapine.

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<sup>68</sup>Folkenberg *supra* note 40.

<sup>69</sup>Patlak *supra* note 3.

<sup>70</sup>Folkenberg *supra* note 40.

<sup>71</sup>*Id.*



The lack of access to treatment during initial marketing and distribution of clozapine, though it had gained FDA approval, was a harbinger of problems to come regarding access to the atypical antipsychotics. FDA approval of the drug did not lead to easy access to the medication by the public. Due to the risk of agranulocytosis and the accompanying threat of product liability to the manufacturer, Sandoz instituted a bundling policy in which it would sell clozapine only as part of a package that included blood monitoring. This system was called the “Clozaril Patient Management System” (“CPMS”).<sup>72</sup> Sandoz had arranged for the blood monitoring to be performed by one of two for-profit companies, which it had under contract.<sup>73</sup> Although the FDA had required a monitoring program as a condition to approve the drug, the requirement did not specify that Sandoz itself or one of its affiliates was to perform the monitoring.<sup>74</sup> On the contrary, in 1990 the FDA wrote to the company in order to protest the labeling of the drug, which appeared to require monitoring by Sandoz (or Sandoz-specified affiliates) alone.<sup>75</sup>

Sandoz claimed that the bundling requirement did not represent a mere marketing ploy by the company as suggested by some opponents of the bundling policy, but that the cost of the drug and the associated monitoring requirement ensured the utilization of the best possible monitoring system by patients using its drug. Gilbert Honigfeld, Sandoz’s business director stated, “We want to give people access, but access in the safest possible manner. We don’t want to get in trouble here. And getting into trouble with a new drug basically means people die and the drug is pulled off the market.”<sup>76</sup>

When introduced to the market, clozapine became one of the most expensive medications in the United States. Sandoz charged approximately \$172 per week or \$9,000 per year per patient for its “bundled” package of medication and monitoring.<sup>77</sup> By comparison, the price of the medication in Europe was far lower,

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<sup>72</sup>Swidler *supra* note 41 at 668.

<sup>73</sup>*Id.*

<sup>74</sup>Spolar *supra* note 49.

<sup>75</sup>*Id.*

<sup>76</sup>*Id.*

<sup>77</sup>Swidler, *supra* note 41 at 668.

reportedly \$20 to \$40 per week per patient!<sup>78</sup> Sandoz explained that the discrepancy in pricing stemmed from the greater exposure the company had to product liability litigation in the United States.<sup>79</sup> This “bundling” arrangement ceased in May of 1991, when Sandoz dropped the bundling requirement due to increasing pressure from Congress, the states,<sup>80</sup> and patient advocacy groups, who claimed that the tying arrangement constituted antitrust violations and price-fixing on a drug over which Sandoz held a monopoly.<sup>81</sup> The manufacturer agreed to sell clozapine to purchasers who could ensure proper blood monitoring.<sup>82</sup>

The removal of the bundling requirement had immediate effects on patient access to the medication. In response to the reduced cost, which had fallen to \$5,400 per year per patient without the tying arrangement, New York announced that it would make clozapine available under its Medicaid program. Two weeks after this announcement, the United States Department of Health and Human Services ordered all State Medicaid programs to pay for clozapine, agreeing in turn to pay for half of the drug and monitoring costs.<sup>83</sup>

Currently, distribution of the drug continues to require that strict monitoring procedures be met. Before initiation of treatment with clozapine, patients must submit a blood sample for a white blood cell count, and must submit thereafter to weekly tests of their white blood cell counts for the first six months of continuous treatment.<sup>84</sup> Provided white blood cell counts remain acceptable, the monitoring may slow to every other week. In addition, after cessation of treatment with clozapine, the patient must submit to further blood tests for an additional four weeks.<sup>85</sup>

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<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> Sandoz settled the antitrust action, agreeing to pay approximately \$20 million to the twenty-nine Plaintiff states. *See Sandoz Settles with States on Clozaril Antitrust Lawsuit*, WASH. POST, Sept. 4, 1992, at F3.

<sup>81</sup> Swidler *supra* note 41 at 670; *see also In re Clozapine Antitrust Litig., Multidist. Litig.* No. 874 (N.D. Ill. 1990); *see* Ron Winslow, *Sandoz Unit Faces States’ Antitrust Suit Over Marketing of Schizophrenia Drug*, WALL ST. J. Dec. 19, 1990, at B8. *See also* Consent Order, FTC Notice, Dkt. C-3385, August 13, 1992 (explaining that consent order issued July 28, 1992 prohibited the company from requiring any purchaser of the drug or patient taking the drug to buy other goods or services from Sandoz or anyone designated by Sandoz. The consent order also required that Sandoz provide a reasonable response to any company’s request for information about patients who have had adverse reactions to clozapine).

<sup>82</sup> Swidler *supra* note 41 at 670.

<sup>83</sup> Swidler *supra* note 41 at 671; *see also* Milt Freudenheim, *Medicaid Payment Ordered for Drug for Schizophrenia*, N.Y. TIMES, May 25, 1991, at A1.

<sup>84</sup> NOVARTIS *supra* note 1 at 5.

<sup>85</sup> *Id.*

Any policy or reform established regarding atypical antipsychotic treatments must require vigilant monitoring. The lack of strict monitoring may, indeed, pose a risk to patients. Dr. Fritz Henn, chairman of the psychiatry department at the State University of New York at Stony Brook, L.I., expressed such a concern. “Many of our patients are in state institutions where the levels of care are variable.”<sup>86</sup> Thus, it is clear that some careful balance must be reached between access and ensuring safe use of the drug.

#### IV. Newer Atypical Antipsychotics: Olanzapine and Risperidone

The acceptance of the use of clozapine by clinicians treating schizophrenic patients cleared a path for the development of newer generations of atypical antipsychotics, most notably, olanzapine and risperidone. Although much research exists confirming the general superiority of the atypical antipsychotics as a class over their conventional or traditional counterparts, scarce research exists regarding one atypical’s superiority over another.<sup>87</sup>

Olanzapine and risperidone claim the same benefits as clozapine, including the treatment of negative as well as positive symptoms of schizophrenia, while avoiding the problems with extrapyramidal symptoms and tardive dyskinesia experienced with traditional antipsychotic medications. Risperidone and olanzapine offer the additional and important benefit of avoiding the potentially fatal condition of agranulocytosis, which poses a high risk to those who undergo treatment with clozapine.

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<sup>86</sup>*New Drug is Said to Help Severe Schizophrenics*, N.Y. TIMES, May 15, 1987, at B12.

<sup>87</sup>In a summary of clinical studies comparing the relative efficacy of clozapine, risperidone and olanzapine, one author stated: “A total of 10 head-to head trials have been conducted comparing various atypical antipsychotics. In these investigations, risperidone has been the most examined and has been included in nine of the 10 trials. Clozapine and olanzapine have also been included in such studies. One point to consider is the different methods used in each of these examinations. They have differed on binding, sample size, patient population, dosing schedules, mean doses, and, of course, outcomes. As clinicians, it is hard to determine which results can be generalized to clinical practice. Most appropriate dosing of these medications is still being investigated; this fact should be taken into account when evaluating head-to-head trials. All of the trials presented have involved relatively small sample sizes.” Donald Rogers, Pharm.D, *Comparing Atypical Antipsychotics*, 19 PSYCHIATRIC TIMES 1 (2002).

Johnson & Johnson introduced its atypical antipsychotic, risperidone, in 1994 under the brand name of “Risperdal.” Those who had an interest in the treatment of schizophrenia welcomed the introduction of the drug due to its detachment from the risks of agranulocytosis and seizure that plagued its predecessor, clozapine.<sup>88</sup> Risperidone, like clozapine, in active comparator studies, proved itself equal or superior to conventional neuroleptic agents in terms of both positive and negative symptom relief.<sup>89</sup> Furthermore, some studies suggest that risperidone outperforms clozapine in treating patients with severe delusions and hallucinations.<sup>90</sup> However, extrapyramidal symptoms frequently emerge with higher dosages of risperidone, though the development of tardive dyskinesia did not evidence itself in trials.<sup>91</sup>

Olanzapine was introduced on October 1, 1996, when the FDA approved the new atypical antipsychotic manufactured by Eli Lilly & Co. under the brand name of “Zyprexa.” Some commentators believe that olanzapine provides many of the benefits of clozapine without some of its more severe negative side-effects.<sup>92</sup> In addition, studies of olanzapine show that the drug has long-term efficacy. Furthermore, the FDA made olanzapine the first drug to receive its approval for the maintenance therapy of schizophrenia.<sup>93</sup> Olanzapine may stand out as the superior atypical antipsychotic due to its effectiveness in treating positive and negative symptoms without the side-effects posed by both clozapine and risperidone.

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<sup>88</sup>Ramsey & Ross *supra* note 32.

<sup>89</sup>*Id.*

<sup>90</sup>Rogers *supra* note 87.

<sup>91</sup>Ramsey & Ross *supra* note 32.

<sup>92</sup>*See infra* note 94.

<sup>93</sup>Ramsey & Ross *supra* note 32.

“Multinational clinical trials comparing olanzapine with conventional neuroleptic agents and placebo have found evidence for improved efficacy in psychosis. One trial, evaluating 1996 patients in 17 countries, showed that olanzapine (5-20 mg per day) was significantly better than haloperidol (5-20 mg per day) in reducing psychotic symptoms. The benefit was especially striking for negative symptoms, and subsequent analyses have indicated that the effect is directly related to the drug’s action on the core deficits of schizophrenia, rather than being secondary to lesser induction of extrapyramidal symptoms or due to an overall superior antipsychotic action. Schizophrenic patients who had comorbid depression also showed more of an antidepressant response to olanzapine than to haloperidol, and in the group overall, changes in quality-of-life indicators favoured olanzapine. Olanzapine patients had fewer extrapyramidal side-effects, a lower dropout rate over the course of the study, and a lesser incidence of tardive dyskinesia over the course of a year. The only frequent (greater than 10%) undesirable side-effects observed were weight gain and drowsiness. . . .”<sup>94</sup>

On the other hand, risperidone may prove to be an attractive alternative to both clozapine and olanzapine due to its more affordable price. A Risperidone Olanzapine Drug Outcomes Study in Schizophrenia (“RODOS”) conducted by the Janssen Research Foundation<sup>95</sup> determined that risperidone reduced the cost of treating schizophrenics on several different levels. First of all, the use of the drug as compared to the use of olanzapine resulted in a savings of \$2.80 per patient per day, or \$1,022 per patient per year, making the cost of olanzapine 50 percent higher than that of risperidone. According to the RODOS study, the results were consistent across the 61 centers, and nine countries included in its study. Furthermore, all inpatient drug use was significantly higher in the olanzapine group than in the risperidone group. And lastly, the RODOS study showed that risperidone-treated patients were discharged sooner than olanzapine-treated patients, resulting in savings due to shortened hospital stays.<sup>96</sup> The cost-effectiveness of risperidone may prove invaluable in providing schizophrenics with treatment in a managed care health care system with extremely regulated and limited resources. Physicians, in making treatment decisions must, of course be mindful of efficacy as well as cost concerns.

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<sup>95</sup>Janssen Research Foundation is a Johnson & Johnson - affiliated organization. <http://www.janssenpharmaceutica.be/about/index.stm>.

<sup>96</sup>*Schizophrenia: newer antipsychotic medicine saves money*, PAIN & CENTRAL NERVOUS SYSTEM WEEK, July 29, 2000, 21-22.

The atypical antipsychotics, generally, have their own share of drawbacks and limitations, which have impacted compliance rates in patients. For example, concerns about weight gain and the consequent development of metabolic abnormalities have caused some patients to discontinue taking their medication.<sup>97</sup> However, given that the resultant weight gain seems to be one of the most consistent side-effects of the atypical antipsychotics, it certainly seems worthy to support them as first-line treatments over the conventional antipsychotics, which cause far more severe and potentially irreversible and/or fatal adverse effects.<sup>98</sup> Furthermore, use of a conventional antipsychotic for first-line treatment may have greater and more severe consequences than the waste of resources alone. Delay of effective treatment reduces the likelihood that the patient will have a good response to therapy.<sup>99</sup> Indeed, studies have shown that when a schizophrenic receives treatment after a relapse, (which is a far greater possibility when undergoing treatment with the conventional antipsychotics) therapeutic responses become successively weaker, emphasizing the need to provide effective treatment as soon as possible and reducing the potential for relapse.<sup>100</sup> In addition, risperidone may provide a solution to the significant problem of compliance.<sup>101</sup> Current research shows that risperidone may soon be available and marketed in a long-acting, injectable form. This new formulation, called “Risperdal Consta” currently awaits the approval of its new drug application with the FDA and regulatory agencies worldwide.<sup>102</sup> The drug utilizes microsphere technology, which gradually releases it into the body, allowing the body to maintain stable blood levels for two weeks.<sup>103</sup> Currently, the only

<sup>97</sup> *Advisory Committee Transcript supra* note 6 at 24.

<sup>98</sup> *Atypical Antipsychotics May Be Used In First-Line Of Brain Disorders*, DOCTOR’S GUIDE, GLOBAL EDITION (1997), at [www.pslgroup.com/dg/4a596.htm](http://www.pslgroup.com/dg/4a596.htm). (The introduction of atypical antipsychotics as first-line medications represents an unrivaled turning point for the more than five million Americans suffering from the most debilitating brain disorders, said NAMI executive director Laurie Flynn. The new drugs offer these individuals renewed hope and exciting new possibilities for full and productive lives. Unfortunately, however, far too many people with chronic mental illnesses are denied access to these life-changing remedies.).

<sup>99</sup> Joan Stephenson, PhD, *Delay in Treating Schizophrenia May Narrow Therapeutic Window of Opportunity*, 282 J. AM. MED. ASS’N, No. 16 (April 26, 2000) at <http://jama.ama-assn.org/issues/v283n16/full/jmn0426-1.html>.

<sup>100</sup> *Id.*

<sup>101</sup> Weidan, Shaw & Mann, *supra* note 24.

<sup>102</sup> *Schizophrenia: New Data Suggest Long-Term Efficacy of Risperidone*, PAIN & CENTRAL NERVOUS SYSTEM WEEK 24 (via NewsRx.com) (Jan. 21, 2002).

<sup>103</sup> *Id.*

available long-acting antipsychotic drugs are the conventional drugs, accompanied by their sometimes-severe side-effects.<sup>104</sup>

The lack of a single, “perfect” treatment for schizophrenia should not discourage physicians, patients, or policy-makers in ensuring that the drugs are made available to patients. On the contrary, policy-makers should work to increase availability and access to the medications so that physicians and patients may make informed decisions as to the best course of treatment for each individual patient. Only this interaction and exchange by physician and patient, made on a case-by-case basis, may accurately determine which individuals would most benefit from each medication. Ideally, reimbursement hurdles, managed care restrictions and threats of tort liability should not overshadow these determinations of efficacy.

V.

The Biological/Physiological Benefits of Atypical Antipsychotics – Treating a  
Physical Illness

“[S]chizophrenia is an eminently treatable disease” similar to diabetes in that medications may be used to treat the symptoms of the disease without necessarily curing the individual of the disorder.<sup>105</sup> “[E]vidence is now overwhelming that brains of persons who have schizophrenia are, as a group different from brains of persons who do not have this disease.”<sup>106</sup> Thus, it seems clear that the current divide between coverage for physical and mental illness, even when the mental illness has a biological basis, exists because of prejudice and stigmatization of the mentally ill.

This stigma results in part from ignorance or a lack of understanding of the nature of severe mental illnesses,

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<sup>104</sup>*Id.*

<sup>105</sup>Brian D. Shannon, *The Brain Gets Sick, Too – The Case for Equal Insurance Coverage for Serious Mental Illness*, 24 ST. MARY’S L.J. 365, 369-70 (1993).

<sup>106</sup>*Id.* at 369.

and also in part from a refusal to believe that the symptoms exhibited by the mentally ill could possibly have a physical basis. “Many members of the public and the insurance industry still view individuals with mental illness as causing their own mental problems. Consequently, this segment of the public believes that persons with mental illness should be able to overcome their illness simply by their own efforts.”<sup>107</sup> However, current scientific evidence should not be dismissed. Moreover, societal ignorance or prejudice should not be supported or tolerated by government regulation (or lack thereof). The maintenance of the disparate treatment given to mental health care as compared to “physiological” health care only perpetuates discriminatory attitudes toward the mentally ill, and should be reformed to address this problematic result.

Should the argument that schizophrenia represents a biological physical illness of the brain prove unconvincing, one may also consider that treatment with atypicals have independently physiologically beneficial effects. The use of atypical antipsychotic medication, including risperidone and olanzapine, also have wider-reaching benefits on *physiological* health as indicated by Tony George, M.D., assistant professor of psychiatry at Yale School of medicine and lead author of a study on smoking and drug use by schizophrenic patients: “[N]ewer medications used to treat schizophrenia also might be helpful for these patients in treating smoking and other types of drug dependencies. . . . And because so many schizophrenics smoke,<sup>108</sup> this finding could have substantial public health implications.”<sup>109</sup> Although smoking may seem a relatively minor and tangential problem to the problem of treating the disorder itself, the shockingly high rates of smoking among schizophrenics should be addressed if possible. Seventy to 90 percent of patients with schizophrenia smoke cigarettes, as compared to 25 percent of smokers in the general population.<sup>110</sup> “Rates of certain diseases, particularly cardiovascular disease, are much higher among schizophrenics.”<sup>111</sup>

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<sup>107</sup>*Id.* at 371.

<sup>108</sup>An estimated 90 percent of schizophrenics smoke. *Advisory Committee Transcript supra* note 6 at 25.

<sup>109</sup>M2 PRESSWIRE, *New Antipsychotic Drugs Combined with Nicotine Patch Help Schizophrenics Quit Smoking*, November 16, 2000, (available on Westlaw).

<sup>110</sup>*Advisory Committee Transcript supra* note 6 at 25.

<sup>111</sup>M2 PRESSWIRE *supra* note 109.



The atypical antipsychotics are particularly effective in curbing smoking by schizophrenics due to the fact that many patients smoke to lessen the movement disorder symptoms that schizophrenics experience when taking traditional antipsychotics such as Haldol and Thorazine.<sup>112</sup> In addition to quit rates alone, the study investigating this theory objectively measured smoking by monitoring carbon monoxide levels, which are a by-product of cigarette smoke. The levels of carbon monoxide were substantially less in patients prescribed the atypical antipsychotics.<sup>113</sup>

As our country enters a period of advanced scientific research and developments, in which access to information regarding the biological and physiological nature of severe mental illnesses such as schizophrenia becomes increasingly available, health care reforms should cast aside outdated beliefs regarding the nature of mental illness. Severe mental illnesses, such as schizophrenia in particular, that have clear physiological causes *as well as* physical or biological consequences should receive health care coverage comparable to that enjoyed by individuals who suffer from other physiological disorders or illnesses.

## VI. State of Mental Health Care in United States

The second-class citizenship status of mental health patients in relation to patients seeking treatment for physiological illnesses has been under attack in the United States in recent years. Increased awareness of the impact of mental health on an individual's well-being continues to shape American health care policy, as well as the attitude of Americans in general toward the mentally ill and their care.

Schizophrenia has been referred to as a “barometer of mental health care policy in this country for decades.”<sup>114</sup>

Thus, by examining the difficulties faced by schizophrenics in receiving medical coverage, we can achieve some sense of how mental health care policy is developing and treated overall. Due to the misunderstood nature of schizophrenia and the stigma associated with the disorder, reforms on schizophrenia have unfortunately

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<sup>112</sup>These drugs cause muscle stiffness and abnormal facial and extremity movement because they block the subclass of dopamine D2 receptors in regions of the brain that control movement. Risperidone and olanzapine block dopamine receptors in motor pathways to a lesser extent. *See* M2 PRESSWIRE, *supra* note 109.

<sup>113</sup>*Id.*

<sup>114</sup>Lehman, *supra* note 13.

been driven less by medical knowledge and more by misguided, though “prevailing social attitudes and beliefs.”<sup>115</sup> The Surgeon General’s Report on Mental Health, issued in 1999, stated that mental and behavioral disorders affect approximately one in five Americans every year.<sup>116</sup> The report discussed the importance of mental health care, stating, “Appreciation of the clinically and economically devastating nature of mental disorders is part of a quiet scientific revolution that not only has documented the extent of the problem, but in recent years has generated many real solutions” and further, that the “artificial centuries-old separation of mind and body” should cease.<sup>117</sup> However, “mental health is often an afterthought, and illnesses of the mind remain shrouded in fear and misunderstanding.”<sup>118</sup>

Historically, mental health services have not received equivalent attention or support as that which is given to health services for those conditions thought to be distinctly physiological. Both private and public funding permit “carve-outs” for mental health coverage, which limit benefits for mental health services relative to physical health benefits.<sup>119</sup> Private insurance coverage customarily restricts mental health benefits to a greater extent, by setting caps on hospital days or outpatient visits, or by imposing spending caps for mental health services.<sup>120</sup> Furthermore, health maintenance organizations (HMOs) customarily establish lifetime or annual spending caps that limit coverage of diseases such as schizophrenia due to the presumed high cost of treatment.<sup>121</sup>

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<sup>115</sup>*Id.*

<sup>116</sup>US DEPARTMENT OF HEALTH AND HUMAN SERVICES, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services, National Institute of Health, National Institute of Mental Health, *Mental Health: A Report of the Surgeon General – Executive Summary* (1999).

<sup>117</sup>Report of Surgeon General (1999).

<sup>118</sup>Tammy Chernin, *Maintaining Mental Health: The new focus is on maximizing benefits and minimizing side-effects*, 145 DRUG TOPICS No. 11, 33 (2001).

<sup>119</sup>Philip J. Boyle & Daniel Callahan, WHAT PRICE MENTAL HEALTH? THE ETHICS AND POLITICS OF SETTING PRIORITIES 4 (1995).

<sup>120</sup>*Id.*

<sup>121</sup>*Id.*

## B. Reform of Mental Health care Policy

### I. Managed Care

The prospect of health care reform in large part requires a resetting of priorities, which is no simple task. Due to rise of the dominance of managed care and an accompanying concern and obsession with costs and allocation of resources within an assumed zero-sum framework, a debate on priorities often takes the form of a choice between alternative treatments or competing populations. Schizophrenic patients may, for example, be forced to compete for mental health resources in order to purchase needed medication such as clozapine, with populations of those who suffer from mild forms and merely episodic forms of mental illness.<sup>122</sup> Considering the costly nature of treatments for schizophrenia (at least in the short-term) prejudice against schizophrenic patients may take the form of preference for treating these milder and non-chronic mental disorders.

“Proponents of managed care argue that it promotes a fundamental moral goal; namely, conserving scarce health-care resources by insuring their efficient distribution. Opponents of managed care criticize the efficiency principle because, *in an effort to balance individual needs against welfarist concerns of society, it undermines the fundamental moral commitment of medical practice – advocacy for the individual patient.*”<sup>123</sup> Indeed, one author suggests that managed care organizations and insurers often obtain “efficiency” by targeting mental health care as an inefficient expense; “by selectively marketing to healthier patient groups, or offering plans that exclude certain treatments, they are able to select enrollees who are likely to use fewer and cheaper services.”<sup>124</sup> Thus, one may easily understand the dilemma schizophrenic patients find themselves in, with regard to receiving coverage for their treatments. Mental health care as a whole remains a target

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<sup>122</sup>*Id.* at 6.

<sup>123</sup>Stephen A. Green, *The Ethics of Managed Mental Health Care*, in PSYCHIATRIC ETHICS 403, (Sidney Bloch, Paul Chodoff, Stephen A. Green ed., 1999) (emphasis added).

<sup>124</sup>*Id.* at 413.

of managed care for cost-cutting. Within this framework, the most costly treatments, which include the atypicals, are continually excluded from coverage or are the target of spending caps of health care plans.

## II. State Coverage issues

Almost every state<sup>125</sup> has adopted managed care in providing some or all of its health care services through the contracting out of their Medicaid services to private HMOs or managed care organizations.<sup>126</sup> Managed care of conditions relating to mental illness or substance abuse have been termed, “managed behavioral health care.”<sup>127</sup> While some states have separate managed care plans for mental health services than they have for other health services, other states have plans that include mental health services in their general plans, but provide an enhanced benefits package for adults with serious mental illnesses, children in or at risk of state custody and children with serious emotional disturbances.<sup>128</sup> “Although highly controversial in the provider community and of great concern to advocates for the mentally ill, the management of behavioral health care services is unlikely to go away, because it is a creature of the drive for cost containment affecting the entire health care system.”<sup>129</sup> Thus, health care reform with the goal of providing schizophrenic patients better access to treatment must operate under the assumption that managed care of mental health care is here to stay.

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<sup>125</sup>Miles F. Shore, M.D. & Allan Beigel, M.D., *The Challenges Posed by Managed Behavioral Health Care*, 334 NEW ENGLAND J. OF MED. NO. 2, 116-119, (1996) (Stating that employers in the private sector have also turned to managed care organizations that provide managed behavioral health care in an effort to reduce the expense of health care, while increasing “the accountability of the system in terms of both quality and value.”).

<sup>126</sup>Susan Stefan, UNEQUAL RIGHTS: DISCRIMINATION AGAINST PEOPLE WITH MENTAL DISABILITIES AND THE AMERICANS WITH DISABILITIES ACT 204 (2001).

<sup>127</sup>Miles F. Shore, M.D. & Allan Beigel, M.D., “The Challenges Posed by Managed Behavioral Health Care,” *The New England Journal of Medicine*, Vol. 334:116-119, January 11, 1996, no. 2. p. 116?

<sup>128</sup>Stefan, *supra* note 126 at 204.

<sup>129</sup>Shore & Beigel, *supra* note 125 at 116.

Formularies are one of the most common cost-containment devices utilized by managed care organizations.<sup>130</sup>

Due to the expense of the atypical antipsychotics they are not surprisingly targeted for exclusion in health care providers' formularies. Efficiency stands as one of the main principles upheld by managed care, leading to a certain "economism," which favors provision of benefits for the treatments and illnesses that demand the least amount of resources.<sup>131</sup> This bias for "less expensive" illnesses places the treatments for chronic mental disorders such as schizophrenia at serious risk of exclusion from formularies.

"Formularies, specifically, may compromise patient care in several ways. Necessary pharmaceuticals may be omitted in the process of formulary compilation, either because consolidation results in pharmaceutical manufacturers favoring their own drugs over the drugs of competitors or because formulary decisions may fail to account sufficiently for variations among individual patients. Some drugs may not provide more benefit than their counterparts on average, but may make a substantial difference to a minority of patients. Eliminating the option of what may be better for some inevitably compromises the care of a small population of patients. *In addition, these compromises may not even be offset by cost savings; increased expenses for a patient who was inadequately treated initially may far outweigh the savings on the drugs with which the patient was treated.*"<sup>132</sup>

As suggested by this argument, short-sighted efforts to reduce the cost of behavioral health care by structuring formularies to exclude full coverage of atypical antipsychotics as *first-line treatments*, may, in fact, result in a greater ultimate health care expense. Physicians unable to exercise their own judgment regarding whether to treat schizophrenic patients with conventional or atypical antipsychotic drugs, and furthermore unable to freely choose *among* atypical antipsychotic alternatives, may be forced to *knowingly* administer medications that will at best have ineffective results and at worst cause severe irreparable harm to the patient. The obligatory, albeit cheaper, conventional antipsychotic treatment will then represent a mere failed attempt at treatment and thus, a total waste of time, resources and funding.

Therefore, the patient, if fortunate enough to receive the needed medication, will ultimately undergo treatment with the atypical antipsychotic at further expense, when the treatment could have been administered

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<sup>130</sup>American Medical Association, Council on Ethical and Judicial Affairs, *Managed Care Cost Containment Involving Prescription Drugs*, 53 FOOD & DRUG L.J. 25, 25 (1998). [Hereinafter *AMA Council*].

<sup>131</sup>Green, *supra* note 123 at 403.

without the previous waste of resources. “Ten studies have proven that unrestricted use of atypical antipsychotics are cost-effective and actually reduce overall health care costs. For example, San Diego County saved \$4,842 per patient per year after patients began taking Risperdal.”<sup>133</sup> Furthermore, as discussed later in this essay, the atypical antipsychotics have additional cost-saving effects, such as a resulting decrease in hospitalization due to the efficacy of these drugs. “A recent study by the USC School of Pharmacy concludes that the average cost of treating schizophrenia is \$19,000 per patient per year. Unrestricted access to the newer medications would result in a net savings to the . . . budget of \$5,000 per patient per year, a 29 percent savings to the total Medi-Cal budget. That savings more than covers the additional \$13 million cost of the medications to the pharmacy budget.”<sup>134</sup>

New York and California provide two examples of states that have attempted to revise their mental health care policies for the specific purpose of providing greater access to atypical antipsychotic treatments. New York’s attempt at reform, however, fell somewhat short of successful in the eyes of patient advocates and physicians, due to the limited nature of physician *discretion* in prescribing the medications. New York’s Medicaid reform attempted to provide access to clozapine without sacrificing concerns about safety, monitoring or the danger of abuse of the health care system by over-prescription of the drug when unnecessary.

“When New York provided Medicaid coverage for Clozapine in July 1991, it imposed a variety of requirements intended to ensure the safe and cost-effective use of the medication. . . . Most significantly, the State required prior approval by the Department of Health, based on clinical eligibility criteria, before a patient would be covered; it also required periodic reconsideration of the patient’s clinical eligibility. Providers were further obligated to agree to provide case management services, primarily to ensure patient compliance with blood monitoring, without any fee enhancement. Only psychiatrists or psychiatric hospital physicians were authorized to prescribe the drug. Finally, Medicaid would only reimburse for the use of Clozapine for active schizophrenia – not for other ‘off label’ uses.”<sup>135</sup>

The limitations defined in the New York reforms provide an example of how behavioral health care reform

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<sup>133</sup> *Elimination of ‘Two Strikes’ Policy for Schizophrenia Drugs Could Save Medi-Cal Program \$17 Million Annually* (May 9, 1997), at [www.schizophrenia.com](http://www.schizophrenia.com).

<sup>134</sup> *Id.*

may prove grand in gesture and intent, but only symbolic in practice. The provision stating that reimbursable uses of the atypicals required prior approval by the FDA, became a problematic administrative hurdle to many seeking coverage of their antipsychotics treatments.

The FDA identifies “approved uses” for prescription drugs,<sup>136</sup> which the drug manufacture lists in its product literature, but physicians may also prescribe drugs for unapproved uses.<sup>137</sup> “The FDA cannot prevent physicians from prescribing drugs for unapproved uses; however, liability concerns or managed health care oversight may prevent physicians from doing so.”<sup>138</sup> Therefore, despite the fact that an “approved use” of clozapine requires prior use and failure of other antipsychotic medications, mental health physicians may prescribe clozapine without the patient actually having tried the conventional antipsychotics, making the use of atypicals as first-line treatments an “unapproved” use. Thus, even if the medical community accepts the atypical antipsychotics as appropriate first-line treatments, schizophrenic patients are met with the problem of reimbursement.

The New York provision denying reimbursement for “off label” or “unapproved” uses presents a problem for mental health physicians and their schizophrenic patients. The reliance on this criterion assumes that the explicitly approved and marketed uses of the atypical antipsychotics are the only safe uses and therefore, the only uses that qualify for reimbursement. However, physicians and pharmacists protested New York’s clozapine access rules.<sup>139</sup> “They complained that the decision to prescribe Clozapine, like decisions to prescribe other drugs, was a clinical judgment in the sole province of the patient and physician.”<sup>140</sup> Indeed, it seems difficult to dispute such a claim or argument. Mental health advocacy groups likewise responded to the New York plan in a predictable fashion, “express[ing] their outrage and accus[ing] the State of trying to

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<sup>136</sup>Ronald Hansen, *FDA Regulation of the Pharmaceutical Industry*, in HAZARDOUS TO OUR HEALTH? FDA REGULATION OF HEALTH CARE PRODUCTS 16 (Robert Higgs ed., 1995) (“Approved” uses are specified by the FDA at the time a new drug is approved.).

<sup>137</sup>Blaschke, Nies & Mamelok, *Principles of Therapeutics*, in GOODMAN & GILMAN’S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 49, 58 (A. Gilman & L. Goodman, eds., 7<sup>th</sup> ed. 1985).

<sup>138</sup>Hansen, *supra* note 136 at 17.

<sup>139</sup>Swidler, *supra* note 41 at 670-71.

<sup>140</sup>*Id.*

block access with red tape, and of discriminating against patients with mental illness by imposing a screening system not imposed on other Medicaid clients.”<sup>141</sup>

Due to the inefficiencies of government agencies in administering claims, the type of plan established by New York illustrates two kinds of problems that may occur with such a behavioral health care coverage scheme. First of all, FDA approval is required in order for a drug label to include certain uses as “approved.”<sup>142</sup> Thus, only those uses that have withstood FDA scrutiny and perhaps more importantly, those uses that have even reached consideration by the FDA, have a chance of surviving the approval process. The inability of the FDA to respond quickly to every request for a new drug approval has often been cited as an administrative hurdle perhaps too great to require FDA consideration before every new use may be added to a drug’s label. Secondly, even if the prescribed use is “approved” the bureaucratic hurdle of receiving Department of Health approval before administering drugs such as clozapine, would present barriers to access and inefficiencies in reimbursement that may prove prohibitive to treatment using the atypical antipsychotics.

“Prior authorization [under managed care formularies, for example], which requires physicians to secure permission from a specialist or other designated person before using high-cost drugs, can unduly discourage optimal drug therapy. Prior authorization requirements also may increase administrative costs.”<sup>143</sup> A serious consequence of the above type of policy, as demonstrated by New York, is that, “physicians registered their displeasure with the prior approval process by simply failing to prescribe Clozapine to anyone.”<sup>144</sup> Other studies have confirmed that despite clinical findings that clearly demonstrate the advantages of prescribing the atypicals, neither they nor the conventional antipsychotics are being utilized optimally.<sup>145</sup>

Plans similar to New York’s reformed behavioral health care policy appear to extend equitable coverage

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<sup>141</sup>*Id.*

<sup>142</sup>Hansen, *supra* note 36.

<sup>143</sup>*AMA Council*, *supra* note 130 at 30.

<sup>144</sup>Swidler, *supra* note 41 at 670-71.

<sup>145</sup>Lamberg, *supra* note 33 (In a survey performed at two public mental health clinics in Los Angeles, the researchers found “that 38% received poor-quality medication management, according to criteria derived from national treatment recommendations, and 52% received inadequate psychosocial care, as defined by lack of case management and family management. Most poor care ... was likely due to factors that can be modified.”).



for severe mental disorders such as schizophrenia. However, in practice, as evidenced by the response of New York’s mental health care physicians, administrative hurdles can create obstacles significant enough to preserve the status quo, where patients lack access to treatment. Indeed, reforms such as those implemented by New York may prove particularly insidious to the project of achieving parity in health care laws, because, at least facially, it *appears* as though the problem of disparate coverage has been remedied.

Yet another serious consequence of using “off label” or “approved” uses as a bright-line cut-off for determining coverage status of patients for atypical antipsychotics is the resulting lack of incentives for drug manufacturers to conduct the supplementary clinical research necessary in order to gain FDA approval for additional uses. Once the drug has been marketed and its initial uses are approved, the additional expense may not be worth the pharmaceutical company’s time or resources.

Therefore, those who are most able to pay may benefit from the medication’s off-label uses (because physicians may still *prescribe* the drugs legally though the uses are not approved), but those who lack adequate medical coverage or who are unable to pay will remain untreated. This dynamic leads to disturbing distributive consequences, where the wealthy receive treatment for a life-threatening disease that severely impacts the quality of life of those it afflicts, while the less wealthy may receive inferior treatment at the least and no treatment at all in the worst case scenario.

One of the FDA’s chief concerns in requiring clinical testing and formal FDA approval in order to label a treatment as an “approved use” stems from a concern that pharmaceutical companies may take advantage of the absence of such a rule and market drugs for uses that may prove dangerous to consumers. Considerable concern existed about unapproved uses of pharmaceuticals and pharmaceutical companies’ marketing

of drugs based on unapproved uses.<sup>146</sup> Pharmaceuticals may often have uses other than those specifically approved by the FDA. Even if the manufacturer is aware of the potential uses during the clinical stages, such uses may not become approved due to the manufacturer's decision not to invest further resources to investigate the additional use or due to the FDA's refusal to designate the claimed use as approved.<sup>147</sup> In the event that additional uses for drugs are discovered after their approval, a pharmaceutical may conduct additional clinical trials and file a supplemental NDA to broaden the claimed uses.<sup>148</sup>

The FDA has expressed concern about pharmaceutical companies sponsoring or publishing articles in journals or other medical sources that list uses other than those specifically approved by the FDA for their medications.<sup>149</sup> The concern stems from the potential for pharmaceutical companies to abuse the current system that allows physicians to prescribe drugs for unapproved uses, by disseminating information within medical communities to make the unapproved uses known, and thus to have their drugs used for those purposes, but to avoid filing supplemental NDA's, thus avoiding the expenditure of additional resources for further clinical testing.<sup>150</sup> However, given the fact that both the FDA and patient advocate groups have previously determined that the atypicals, though potentially dangerous, are "a risk worth taking," restraints such as this one, permitting only reimbursement of approved uses should be avoided. Only by affording coverage of atypicals as first-line uses (which are currently not approved for clozapine, for example) may patients receive optimal treatment.

Though New York's efforts in providing coverage for atypical anti-psychotic treatments began in a positive direction for schizophrenic patients, clearly, the needs of the schizophrenic community and of their treating physicians were not met by the limited coverage and stringent requirements of the plan.

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<sup>146</sup>Hansen, *supra* note 136 at 16.

<sup>147</sup>*Id.* at 16-17.

<sup>148</sup>*Id.* at 17.

<sup>149</sup>*Id.*

<sup>150</sup>*Id.*

Some years later, in 1997, California followed in the footsteps of New York in providing reimbursement for atypical antipsychotics, and went even further in providing access to treatment by lifting restrictions similar to those included in the New York plan. The Department of Health Services for California lifted its former Medi-Cal restriction, which required prior authorization for reimbursement, by adding all three atypical antipsychotics medications to the list of drugs available to Medi-Cal recipients.<sup>151</sup>

More and more states are becoming increasingly aware of the importance of mental health care and are responding to this new information by enacting their own parity laws.<sup>152</sup> However, optimism about a transformation of health care coverage through state action alone should be tempered by other considerations. “[W]ith a slowing economy, right-minded state lawmakers and behavioral health agencies suddenly find themselves facing tough choices when it comes to coverage of new generation schizophrenia drugs for special populations.”<sup>153</sup>

### III. Incentives

Publicly funded managed care presents both a barrier and an opportunity for schizophrenic patients. The obstacles appear mainly due to managed care’s cost containment-centered policies. Importantly, managed care presents an opportunity for more efficient and better care for mental health patients by opening a path-

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<sup>151</sup>5 No. 20 Cal. Health L. Monitor 7 (1997).

<sup>152</sup>United States General Accounting Office, Mental Health Parity Act: *Despite New Federal Standards, Mental Health Benefits Remain Limited*, GAO/HEHS-00-95 (2000) (indicating that twenty-nine states have enacted mental health parity laws including greater coverage than that required in the Mental Health Parity Act of 1996), available at [http://www.access.gpo.gov/su\\_docs/aces/aces160.shtml](http://www.access.gpo.gov/su_docs/aces/aces160.shtml).

<sup>153</sup>*Shrinking State Purse Squeezes N.C. Schizophrenia Drug Fund*, BEHAVIORAL HEALTH BUSINESS NEWS, (Jul. 12, 2001), at <http://www.psybermetrics.com/resources/20010712-nc.asp>.

way for integration of primary and mental health specialty care.<sup>154</sup> Such coordination would not only ensure that schizophrenic patients receive proper medical care and monitoring, but would also provide an opportunity for early detection and intervention.<sup>155</sup> Currently, managed care policies typically contain “carve-outs” for mental health care. While these carve-outs may help protect resources set aside for mental health care, a more efficient alternative, both cost-wise and care-wise, may be to stipulate in managed care contracts a coordination between behavioral health care providers and managed care providers, particularly for patients with severe mental illness.<sup>156</sup>

One of the primary complaints against managed care relates to physician discretion over patient care. The criticism is that health care administrators, rather than physicians, are increasingly influencing pharmaceutical utilization decisions.<sup>157</sup> Briefly stated, the shift in control has occurred due to the decisions made by HMOs or other health care plans to restrict their drug reimbursement formularies to “encourage” the utilization of less expensive or generic drugs.<sup>158</sup> Furthermore, drug manufacturers are faced with the choice of either offering HMOs significant discounts on drugs, or otherwise face the exclusion of their drugs from the plans’ formularies. The shift in control to health care administrators has the troubling result of focusing on cost, rather than effectiveness of the medications in making treatment decisions.<sup>159</sup>

The pressure felt by drug manufacturers to either lower their costs or face potential failure in the marketing of their medications due to lack of prescription by physicians has consequences outside of those impacting the pharmaceutical companies alone. Such pressures result in a disincentive for drug manufacturers to develop still other effective medications and in any event negatively influences the research and development

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<sup>154</sup>Lehman, *supra* note 13.

<sup>155</sup>*Id.*

<sup>156</sup>*Id.*

<sup>157</sup>Hansen, *supra* note 136 at 14.

<sup>158</sup>*Id.*

<sup>159</sup>*Id.*

investment incentives of pharmaceutical firms.<sup>160</sup>

The FDA's regulatory involvement also affects research and development incentives of pharmaceutical companies. The FDA requires approval of new drugs prior to their marketing.<sup>161</sup> "The FDA's influence extends to the research and development process leading up to market approval as well as to the manufacturing of the product and the marketing claims that the firm can make."<sup>162</sup> Therefore, the FDA's decisions on drug approvals affect the costs of developing drugs and the availability of new innovations in treatment, as well as influencing incentives by drug companies to further their research and development.<sup>163</sup> This positive reinforcement of drug research was evidenced by FDA approval of clozapine in the 1970s, which has led to the development of new generations of atypical antipsychotics such as risperidone and olanzapine. These new generations of atypical antipsychotics offer the potential for increased efficacy, better patient compliance with treatment, decreased chance of severe side-effects, reduced relapse potential, and importantly, are offered at a far lesser expense.

#### IV. Private Providers

The majority of Americans who have private health care coverage receive such coverage through their employers.<sup>164</sup> Although most of these employer-provided plans include some mental health care coverage, most severely restrict the extent of coverage for mental health care by placing caps on hospital stays or outpatient visits, and by requiring a higher percentage co-pay for those seeking treatment of mental disorders.<sup>165</sup> With chronic mental disorders such as schizophrenia, one can imagine that these limited resources are rapidly depleted, leaving patients with no recourse for funding of treatments such as the atypicals that are critical to their mental health. Thus, federal legislation bringing uniformity to health care policies across the nation

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<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> *Id.*

<sup>164</sup> See Thomas G. McGuire, *Predicting the Costs of Mental Health Benefits*, 72 MILBANK Q. 3, 4 (1994).

<sup>165</sup> See Sharon Bee & Mary Jo Gibson, *Mental Health Parity: An Overview of Recent Legislation*, AARP Public Policy Institute Research Summary, 1 (1998), at [http://research.aarp.org/health/fs69\\_mental.html](http://research.aarp.org/health/fs69_mental.html).

would provide relief to the large population of Americans who require additional reimbursement in order to treat their mental conditions.

Though more and more states are joining the effort to offer parity in insurance coverage to mentally ill citizens, federal action must supplement the state efforts in order to achieve a comprehensive scheme of parity legislation.

“Although these state mandates reach a number of persons with mental illness, they do not go far enough because of existing federal law. State legislatures have the authority to mandate coverage levels for mental illness (or other ailments) as part of their power to regulate insurance. Indeed, the Supreme Court has upheld the states’ right to impose mandates for mental illness coverage on insurers. On the other hand, the Court has also determined that the Employee Retirement Income Security Act (“ERISA”) preempts the ability of the states to impose similar mandates on fully self-insured employee benefit plans. In turn, lower courts have determined that fully self-insured health care plans do not constitute insurance and, accordingly, are not subject to state regulation. Thus, state statutory mandates cannot direct coverage for many employed citizens because their employers have decided to self-insure.”<sup>166</sup>

Despite the need for federal legislation for parity, federal efforts at mandating mental health parity through enactments such as the Mental Health Parity Act of 1996, remain ineffective in practice due to the flexibility offered to private employers in formulating their insurance policies (discussed below).

## **C. Considerations for Reforming Policy**

### **I. A Non-Discrimination Standard**

Health care reform meant to address mental health issues can take on several different approaches. At a minimum, one approach could require non-discrimination against the mentally ill. However, optimally beneficial health care reform for the mentally ill would provide parity in the form of either equal funding or equal treatment on the same conditions and terms as physical health services.<sup>167</sup>

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<sup>167</sup>Boyle & Callahan, *supra* note 114 at 5.

The inequitable treatment of the mentally ill with regard to health care coverage represents a mere piece of a larger story of discrimination experienced by the community. Mentally ill patients face potential discrimination in many facets of their lives. They may be excluded or overlooked in employment, education, health care, insurance, misrepresented or degraded by media or experience damaged or discriminatory family, romantic, or other personal relationships.<sup>168</sup> In limited ways, the mentally ill may use the legal system to battle such discrimination. Of particular relevance to this discussion is the ability of schizophrenics to use the legal system in order to obtain parity in insurance coverage of mental disabilities on the level of the coverage offered to patients with physical disabilities. Significantly, discrimination against those with mental handicaps is not represented by single, discrete events that are easily addressed through legal action. “It is not only that people are rejected by their family and shunned by their friends; dismissed from school; scrutinized uneasily or fired at work; patronized by doctors and refused coverage by insurance companies; denied with institutionalization, but also that all of these things happen in interrelated and long-term ways.”<sup>169</sup>

## II. Who should decide?

The democratic process may not be the best or fairest means of determining priorities when it comes to reallocating resources or reprioritizing health care considerations. Alternatives exist, such as the use of experts or deference to public officials.<sup>170</sup> However, in order to protect the legitimacy of our democratic system and to protect public officials willing to make hard decisions, one consequence may be that such decisions must be made behind closed doors. Furthermore, some advocates of keeping this decision-making progress more out of the public’s view propose that “patterns of invidious bias against persons with mental illness are so rampant throughout society that the decisions must be made by knowledgeable and sympathetic

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<sup>168</sup>Stefan, *supra* note 126 at 4.

<sup>169</sup>*Id.*

<sup>170</sup>Boyle & Callahan, *supra* note 119 at 33.

specialists or officials.”<sup>171</sup>

A proposal advocating that officials not listen blindly to majority rule is not one so foreign to the American way of policy-making. For example, the Civil Rights Movement and in particular Title VII have been discussed using similar language – the need for government officials to set policy in the face of a hostile or unwilling majority for the establishment of a policy thought to distribute a just end. In fact, one of Title VII’s purposes was to *change* majority opinions about populations that had been historically discriminated against– the idea being the removing barriers to those minority populations would dispel certain stereotypes and stigmas attached to being members of those groups, which would thereby lead to a more integrated and functional community. Perhaps the implementation of a non-discrimination standard in mental health legislation would likewise dispel myths and stereotypes attached to the mentally ill.

III.

#### Legislation

In a hearing before the Senate on the possible reauthorization of the Mental Health Parity Act, the final report to Congress by the National Advisory Mental Health Council stated,

*The challenge for the coming decade is to develop clear standards based on the best evidence and clinical judgment so that parity has substance in implementation as well as in concept. Parity is not simply some match in service limits to what a medical or surgical patient experiences. It should be a configuration of management strategies fitted to careful assessment of patients’ needs and a response that is consistent with our best scientific knowledge.*<sup>172</sup>

Hope exists for schizophrenic individuals seeking resources for treatment. Medicare currently provides the primary health care coverage for the 5,000,000 non-elderly, disabled people on Social Security Disability

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<sup>171</sup>*Id.*



Insurance.<sup>173</sup> Benefits provided by Medicare reflect an “outdated bias toward institutionally based service delivery” that discriminates against mentally ill Americans under its coverage.<sup>174</sup> Fortunately, Congress has, consistent with the rising national awareness of the need for resources for behavioral health care, flirted with legislation to address the interests of the mentally ill. A bill, entitled the “Medicare Mental Health Modernization Act of 2001”<sup>175</sup> proposes to eliminate Medicare’s 190-day lifetime cap on inpatient psychiatric services.<sup>176</sup> The bill further provided for the reduction of the 80 percent co-pay for outpatient mental health services to a 20 percent co-pay, similar to the share charged for other outpatient care.<sup>177</sup> Though the legislation still awaits passage, if the Act were to become law, Medicare would offer equal coverage for mental illnesses and physical illnesses. Furthermore, the bill as written seeks to include coverage for community-based mental health services, which would prove invaluable to the treatment of schizophrenic patients and would certainly assist in preventing relapse episodes in schizophrenic patients.<sup>178</sup>

The Medicare Mental Health Modernization Act of 2001 is currently still under consideration, but has received the resounding support of mentally ill patient advocate groups such as the National Alliance for the Mentally Ill (“NAMI”).<sup>179</sup> The support for parity stems from the frustration by the mentally ill community with the long history of unequal treatment for mentally ill patients in public and private health care provisions alike.

NAMI has pointed out that Medicare imposes conditions and limitations that even private insurance plans would not impose upon treatment for mental illness. Such conditions include “no coverage for outpatient

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<sup>173</sup>*Medicare Mental Health Modernization Act*, *supra* note 8 at 4.

<sup>174</sup>*Id.*

<sup>175</sup>*Medicare Mental Health Modernization Act*, *supra* note 8.

<sup>176</sup>*Id.*

<sup>177</sup>*Id.*

<sup>178</sup>Chernin, *supra* note 118.

<sup>179</sup>Statement and Letter from NAMI President Jackie Shannon in support of the Medicare Mental Health Modernization Act of 2001, at <http://www.nami.org/update/20010409.html>.

prescription drugs, a 50% co-payment requirement for outpatient services and 190-day lifetime limit on inpatient days.” These conditions apply only to mental illness to the exclusion of other medical conditions.<sup>180</sup> Other criticisms include the suggestion that inequities result from Medicare’s tendency to “too often focus only on the needs of elderly beneficiaries.”<sup>181</sup> It is evident that until recently, the needs of the mentally ill community have been either ignored or misunderstood. However, current attempts at legislation represent at least an effort by Congress to address inequities in coverage for this neglected community.

Proponents of mental health parity obtained one victory in 1996, when Congress passed “The Mental Health Parity Act of 1996”.<sup>182</sup> The Act represented an intended compromise between supporters of full parity and opponents who argued that full parity in coverage would bankrupt insurance companies.<sup>183</sup> The act requires that for plan years beginning in January 1, 1998, and ending October 1, 2001, the group health plans for companies with greater than 50 employees that provide mental health coverage must provide equal lifetime benefit caps.<sup>184</sup> An exception exists for companies that can demonstrate that this requirement would raise their health insurance costs by one percent or more per year.<sup>185</sup>

Vocal opposition followed the passage of the act, due to a fear that the legislation would cause an explosion of health care costs for employers in the private sector, in particular. However, the fears of opponents were misplaced. The actual realized benefits attributable to the Act have been largely illusory.<sup>186</sup> First of all, the

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<sup>180</sup>*Id.*

<sup>181</sup>*Id.*

<sup>182</sup>*Mental Health Parity Act of 1996*, Pub. L. No. 104-204 § 712, 110 Stat. 2944, 2945-47 (codified at 29 U.S.C. § 1185a (1994 and Supp. IV 1998)).

<sup>183</sup>Stefan, *supra* note 126 at 278.

<sup>184</sup>Stefan, *supra* note 126 at 278; P.L. 104-204, 110 Stat. 2874; 42 U.S.C. Sec. 300gg-5 (1996)

<sup>185</sup>Stefan, *supra* note 126 at 278.

<sup>186</sup>*Id.*

one percent exception mentioned above most likely favors employers who offer the most egregious disparities in coverage leading to two results. One consequence of the exception is that employers who are the worst offenders of mental health parity are the very employers that are exempted from compliance with the act! Another consequence of the exception is that it gives employers an *incentive* to create a *greater* disparity in the coverage of mental versus physical illnesses, so that they may make a showing that compliance with the parity requirement would raise their health care costs above the one percent cut-off.

Lobbyists for the mentally ill have responded to the one percent exception with suggested alternatives. These advocates<sup>187</sup> have proposed that requests for exemptions by employers undergo formal review and approval by the government.<sup>188</sup> Anticipating that enforcement or monitoring by the government may prove to be problematic due to a lack of resources or lack of stringency of review, the lobbyists have further proposed that advocates for the mentally ill be permitted to inspect cost estimates and data supporting employer applications for exemption.<sup>189</sup> Predictably, employers have resisted such suggestions, stating that random audits alone will ensure compliance.<sup>190</sup> Congress's task in formulating effective parity legislation must create a careful balance between providing parity and respecting employers' liberty interests in maintaining their businesses and employees as they judge appropriate.

The policy implications of the Mental Health Parity Act extend still further, but potentially to the *detriment* of those meant to benefit from its enactment. The passage of this legislation led to some unexpected consequences in interpretations of the Americans with Disabilities Act that adversely affected the interests of the mentally ill. For example, courts have used the legislation as support for holdings that the ADA does not apply to health insurance, because Congress's separate legislation explicitly in the area of insurance

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<sup>187</sup>Robert Pear, *Parity in Mental Health Benefits May be Diluted by White House*, N.Y. TIMES, October 21, 1997 ( Advocates include Coalition for Fairness in Mental Illness Coverage, which includes the National Alliance for the Mentally, Ill, the National Mental Health Association, the American Psychiatric Association, the American Psychological Association and the American Medical Association) available at [www.ocdhelp.org/diane/legislative.html](http://www.ocdhelp.org/diane/legislative.html).

<sup>188</sup>*Id.*

<sup>189</sup>*Id.*

<sup>190</sup>*Id.*

shows that the two are distinct in coverage.<sup>191</sup> Moreover, the parity legislation has similarly been used to argue that the ADA does not apply to disability benefits, despite the fact that the Mental Health Parity Act does not itself cover disability benefits.<sup>192</sup>

It appears that the disadvantages of the Act may outweigh any real benefits gained from its passage, due to the ability of health plans to maneuver through loopholes in order to escape requirements that may have any real impact on coverage. For example, because group insurance plans are yet free to limit actual office visits and to limit reimbursement paid for each visit, the “equal” lifetime benefit cap set for mental health services may never in reality be reached.<sup>193</sup> Furthermore, under the Mental Health Parity Act of 1996, health plans may implement or continue to use disparate co-payment charges for mental health and physical illness, as well as providing disparate coverage for inpatient and outpatient care.<sup>194</sup> The Act certainly does not represent an airtight effort by Congress to provide equal access to medical resources to the mentally ill. The Medicare Modernization Act of 2001 represents a step further in the direction of accessing true parity, but the fate of the bill as yet remains uncertain.

As for the financial impact on insurance companies, studies show that they may actually be turning a profit from the increased coverage required by the parity legislation rather than suffering from increased costs. Insurance companies that provide parity in coverage charge between 7.5 percent and 21 percent more than standard premium costs.<sup>195</sup> However, the actual increase in cost for providing full parity does not appear to justify this level of price increase.<sup>196</sup> Still, when considering the impact real full parity would have on policy

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<sup>191</sup>Stefan, *supra* note 126 at 279; *see also* Moddero v. King, 82 F.3d 1059 (D.C.C. 1996).

<sup>192</sup>Stefan, *supra* note 126 at 279; *see also* Ford v. Schering-Plough, 145 F.3d 601, 610 (3<sup>rd</sup> Cir. 1998); EEOC v. CAN, 96 F.3d 1039, 1044 (7<sup>th</sup> Cir. 1996); Parker v. Metropolitan Life, 121 F.3d at 1017-1018 (1997); Rogers v. Department of Health and Environmental Control, 174 F.3d 431, 436 (4<sup>th</sup> Cir. 1999); Connors v. Maine Medical Center, 42 F.Supp. 2d 34 (D. Me. 1999).

<sup>193</sup>Stefan, *supra* note 126 at 279.

<sup>194</sup>*Id.*

<sup>195</sup>*Id.* at 285

<sup>196</sup>*Id.*

premiums, the effect would remain relatively small *even if* the realization of parity resulted in a significant increase in the use of mental health services, due to the fact that mental health treatment expenditures as a whole represent a relatively small fraction of all health expenditures.<sup>197</sup>

#### **D. Cost-Effectiveness of Providing Access to Atypical Antipsychotic Treatments**

In evaluating the cost-effectiveness of the atypical antipsychotic agents, factors included in the decision-making process should “focus on changes in symptoms, substance abuse, suicide, aggression, hostility, functional status, access to and use of resources and opportunities, life satisfaction, family well-being, and patient satisfaction with intervention.”<sup>198</sup>

An attempt at reformulating or revising current mental health care policy may not, however, ignore the economic consequences that such a reform will have on existing resources for health care. The ever-rising cost of health care continues to push the bounds of both public and private budgets. Opponents of providing greater health care coverage claim that rising health insurance costs are, for example, disadvantaging American corporations from competing in American markets due to the rising costs of employees’ and retirees’ health insurance.<sup>199</sup> Many international competitors benefit from lower overhead, lower prices and thus greater competitive advantage afforded by their governments’ funding of health services in those countries.<sup>200</sup> “It is not likely that society can curb the accelerating cost of health services and at the same time offer everyone every service of any possible benefit. Choices will have to be made about what services are more or less vital or expendable.”<sup>201</sup>

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<sup>197</sup>Stefan, *supra* note 126 at 285.

<sup>198</sup>*Atypical Antipsychotics: Administrative Issues and Cost Differentiation*, CONTINUING PHARMACEUTICAL EDUCATION, at <http://mesinc.com/education/monographs2/cme002/content/14.html>.

<sup>199</sup>Boyle & Callahan, *supra* note 119 at 7.

<sup>200</sup>*Id.*

<sup>201</sup>*Id.*

Behavioral health care reform may reconcile the need for cost-effective drugs and the need for access to the atypical antipsychotics. Two arguments in particular suggest that providing atypical antipsychotics as first-line treatments may indeed be a cost-effective practice. First of all, the atypical antipsychotics prove more effective than the conventional antipsychotics, which results in a reduced need for hospitalization and use of additional medical resources. Secondly, the introduction of newer, more affordable, and less dangerous atypical antipsychotics such as risperidone and olanzapine may render the debate on the costs of clozapine under our current health care system less relevant.<sup>202</sup>

The controversy and reluctance to supply these prescription drugs to patients using public funds or managed care relies on an underlying assumption – that the net costs of the drugs will be more than that of the current costs already expended in supporting the large number of schizophrenics who are chronically and totally disabled due to the lack of effective treatment of the illness. As a matter of fact, studies have shown that treatment with atypical antipsychotics such as clozapine for treatment-resistant populations<sup>203</sup> actually decreases the cost of treatment of schizophrenics significantly primarily due to a dramatic decrease in the frequency and cost of rehospitalization.<sup>204</sup> One quote estimates that keeping patients out of the hospital a mere five to ten days a year will “easily [ ] cover the roughly \$2000 cost of an entire year’s medication.”<sup>205</sup> In addition, the greater tolerability of the atypical antipsychotics may result in greater patient compliance with drug therapy, thus reducing the amount of rehospitalization. “Even though the newer agents are considerably more expensive, their downstream cost benefits justify more widespread use... For example, in large state or V.A. hospitals, it might be possible to close one psychiatric unit or ward as the inpatient population

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<sup>202</sup>Though, keep in mind that the newer antipsychotics may not be as effective as clozapine. As shown in notes 87-96, risperidone and olanzapine do appear to exhibit substantially similar benefits as clozapine, as well as some further benefits such as avoiding severe side-effects, but extensive research has not been conducted to confirm the equal efficacy of these drugs with clozapine.

<sup>203</sup>“Treatment-resistant populations” includes those who have not adequately responded to conventional/typical antipsychotics. The use of the atypical antipsychotics as a treatment for those populations is consistent with the FDA’s approval requirements.

<sup>204</sup>H.Y. Meltzer, P. Cola, et. al., *Cost Effectiveness of Clozapine in Neuroleptic-Resistant Schizophrenia*, 150 AM. J. OF PSYCHIATRY, Issue 11, 1630-38 (1993)

<sup>205</sup>“New Medications Aid Cognition in Schizophrenia,” 280 J. AM. MED. ASS’N, No. 11 (September 16, 1998), *available at* <http://jama.ama-assn.org/issues/v280n11/ffull/jmn0916-2.html>.

decreases.”<sup>206</sup>

The incidence of schizophrenia itself, left untreated, translates into excessive poverty, due to the under- and unemployment of these patients, further making these individuals dependent on government assistance.<sup>207</sup>

Passage of health care reform bills such as the Medicare Mental Health Modernization Act may “ensure that Medicare beneficiaries with severe mental illnesses are able to access non-discriminatory coverage that will allow them to work and reach their full potential.”<sup>208</sup>

Clozapine clearly presents a significant health risk to the patients who attempt to benefit from its use. Thus, a conservative point of view regarding the United States’ health care resources may argue that the supply of such hazardous drugs should not become a priority on the country’s health care agenda. Commentators siding with this view may further argue that the government should divert needed resources elsewhere, where the funds would provide much needed health care via other drugs and medical needs with more definite benefits to patients.

However, resources allocated toward provision of clozapine to patients would not be wasted. As the product literature indicates, clozapine is not a treatment in danger of being overutilized by the medical community. Its use is heavily monitored and any unnecessary treatments with the medication will promptly cease due to the dangers associated with its use. Thus, clozapine comes with a built-in safeguard against over-distribution of the drug. Only those who clearly benefit from its use will obtain or continue to obtain the medication.<sup>209</sup>

In addition, the cost of clozapine may be lowered through increased competition with newer and more af-

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<sup>206</sup>The Schizophrenia Homepage, *supra* note 2.

<sup>207</sup>Lehman, *supra* note 13.

<sup>208</sup>Shannon *supra* note 179.

<sup>209</sup>However, it is worth mentioning that a successful schizophrenia treatment drug reimbursement program may become a “victim of its own success,” as demonstrated by North Carolina’s attempt to broaden access to the atypical antipsychotics through a special fund set aside for the provision of atypical antipsychotics to schizophrenic patients in need. The program became so successful in broadening access that the number of clients covered by the fund created a strain on the state’s resources. Behavioral Health Business News, *supra* note 153. Thus, one opposing health care coverage of atypical antipsychotics may argue that, although improving access to the drugs may reduce the cost of treatment of schizophrenia *per patient*, the number of treatment-seeking patients may increase to such an extent that the *overall* cost of treating schizophrenics may indeed increase. However, to argue that broadening access to such an extent that those in need will actually seek help represents a *negative* effect of providing mental health care coverage emphasizes the need to shut out all concerns excepting cost in making evaluations of whether to provide coverage.

fordable drugs (such as the injectable form of risperdal). Physicians treating their patients for schizophrenia should have the freedom to select whichever of the atypical antipsychotics they feel is most appropriate for the individual patient. “Each of the atypical antipsychotics has its niche with its own set of negative factors attached to it, necessitating the fine-tuning of each agent for each individual patient.”<sup>210</sup>

The need for providing medications with lasting effects, thereby reducing the possibility of relapse is key to both improving the quality of life for schizophrenics and in cutting costs due to repeat hospitalizations. The American Psychiatric Association estimates that between 20 percent and 50 percent of people with schizophrenia who are treated with medication are rehospitalized each year.<sup>211</sup> Twenty percent of patients who remain on medication will relapse within one year, while 70 percent of patients who discontinue their medication will relapse within the same time period.<sup>212</sup> One study estimates that patients taking Risperdal take a significantly longer time to relapse than those on haloperidol, a conventional antipsychotic that “was long considered the gold standard for treatment of psychosis.”<sup>213</sup>

As technology rapidly evolves in the area of antipsychotic treatments, such as the injectable forms of the atypical risperdal, which is currently awaiting FDA approval, in creating policy, there are several concerns that must be balanced. Concern for patients’ access to needed medication and physician autonomy to prescribe those medications is understandably of paramount concern.

The establishment of spending caps on drug therapy may further unnecessarily increase mental health care costs. One study demonstrated that a monthly spending cap on the coverage for the cost of psychotropic prescription drugs, including antipsychotics, “can increase the use of acute mental health services among

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<sup>210</sup>Chernin, *supra* note 118 at 33.

<sup>211</sup>*Schizophrenia: Risperdal Can Decrease Risk of Relapse in Long-Term Treatment Protocol*, DRUG WEEK 23 (February 1, 2002).

<sup>212</sup>*AMA Council*, *supra* note 130 at 22.

<sup>213</sup>DRUG WEEK, *supra* note 211.



low-income patients with chronic mental illnesses and increase costs to the government, even aside from the increases caused in pain and suffering on the part of the patients.”<sup>214</sup> The study demonstrated that a cap on mental health coverage resulted in an immediate and sustained decrease in the amount of usage of antipsychotics and other mental health treatments.<sup>215</sup> “The resulting increase in agitation and in the frequency of psychotic episodes would increase the need for emergency mental health services and partial hospitalization (full-day or half-day treatment programs) at community mental health centers and the frequency of admissions to psychiatric hospitals, thereby shifting costs from the federal-state Medicaid program to state mental health programs.”<sup>216</sup>

Significantly, even a small reduction in reimbursement for antipsychotic medications can result in “substantial unintended effects on low-income people with chronic mental illnesses.”<sup>217</sup> The disruptions caused in successful treatments or the exacerbation of mental illnesses such as schizophrenia may, in the short-term result in cost reductions, but will lead to immediate or, at the very least, a long-term increase in the use of acute mental health care services, which will result in an ultimate increase in the cost of health care.

Drug reimbursement caps due to the chronic nature of schizophrenia especially jeopardize the welfare of schizophrenic patients. “Patients on maintenance drug therapy for chronic conditions are especially endangered when access to pharmaceuticals is limited by a prescription cap. In one study of schizophrenic patients on Medicaid, hospitalizations rose significantly with the introduction of prescription caps.”<sup>218</sup> Thus, argu-

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<sup>214</sup>Stephen B. Soumerai, Thomas J. McLaughlin, et al., *Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia*, 331 NEW ENGLAND J. OF MED. No. 10, 650-655 (1994).

<sup>215</sup>*Id.*

<sup>216</sup>*Id.* (There was an increase in the administration of anti-psychotic agents at the CMHCs, which are funded by the state mental health systems.)

<sup>217</sup>*Id.*

<sup>218</sup>*Managed Care Cost Containment Involving Prescription Drugs*, 53 FOOD & DRUG L. J. 25, 30 (1998), by American Medical

ments that the provision of equitable coverage for the atypicals would raise the costs of health care to such an extent that health care resources as a whole would become scarce is an empirically unsupported argument. Indeed, the opposite seems to be true. The analysis accompanying the empirical results of studies such as the one mentioned above suggests that, in the long-term, the population of schizophrenics, the institutions that support the funding of their mental health care *and* society at large stand to benefit from the provision of access to the atypicals.

### **Conclusion**

Atypical antipsychotic medications have revolutionized the treatment of schizophrenia. Schizophrenic individuals have the ability to overcome their cognitive dysfunction and anti-social behavior through the use of these drugs, making their lives more complete and fulfilling, while alleviating pressure placed on medical resources in hospitals and other in-patient care facilities.

Members of the schizophrenic community, as part of the larger community of mentally ill individuals, through their experience in seeking sufficient resources for the treatment of their disorder, have illustrated the difficulties faced by the mentally ill in securing funding for health care. Due to the greater awareness of the nature of schizophrenia and other severe mental illnesses (particularly those with a physiological basis), regulation by federal and state governments should provide for the equitable treatment of these illnesses as compared to their “wholly physiological” counterparts. Though progress appears slow and uncertain, the rising education about the nature of mental illness generally will hopefully lead to the progressive legislation that will ensure the coverage of these necessary treatments for schizophrenia.

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Association, Council on Ethical and Judicial Affairs.